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Attorneys for Defendants

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES, Plaintiffs, v. UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, LAWRENCE LIVERMORE NATIONAL LABORATORY, Defendants.	Case No. 08-cv-1372-SBA NOTICE OF LODGING OF SUPPLEMENT TO THE ADMINISTRATIVE RECORD FOR FINAL REVISED ENVIRONMENTAL ASSESSMENT FOR PROPOSED BSL-3 FACILITY AT LAWRENCE LIVERMORE NATIONAL LABORATORY

Defendants hereby lodge with the Court documents supplemental to the previously filed Administrative Record for the challenged Bio-Safety Level 3 Facility at Lawrence Livermore National Laboratory. Pursuant to stipulation (see Dkt. No. 34), the parties have conferred and agree that the documents attached as Exhibit 1, which are numbered AR 124 to AR 131, are appropriately part of the administrative record. Attached as Exhibit 2 is a revised index to the administrative record.

Dated this 27th day of May, 2008.

Respectfully submitted,
RONALD J. TENPAS
Assistant Attorney General

/s/ Barclay T. Samford
BARCLAY T. SAMFORD
Trial Attorney
U.S. Department of Justice
Environment & Natural Resources Division
1961 Stout Street, 8th Floor
Denver, CO 80294

Exhibit 1

Attached to Notice of Lodging of Supp. to the Administrative Record
08-cv-1372-SBA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

TO: Alan Casamajor, Responsible Official
Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, CA 94550
FAX: (925) 423-3110

FR: Centers for Disease Control and Prevention (CDC), Select Agent Program

RE: Apparent Violation of 42 CFR § 73.16 (Transfers)

DATE: September 22, 2005

The Centers for Disease Control and Prevention (CDC), Select Agent Program is investigating allegations that Lawrence Livermore National Laboratory may have failed to comply with all applicable laws concerning package and shipping (see 42 C.F.R. Part § 73.16 (i)) during the shipment of vials containing *Bacillus anthracis* to Midwest Research Institute – Florida Division (CDC authorization number: CEA001233 and CEA001275) and American Type Culture Collection (CDC authorization number: CEA001274).

Receipt of this letter serves as notice that approval for any transfers already issued by the CDC Select Agent Program but have not been transferred are void and that no further transfers will be approved until the CDC Select Agent Program has been able to investigate and resolve the issues raised by these allegations.

The CDC Select Agent Program is requesting information regarding how these transfers (CDC authorization numbers: CEA001233, CEA001274 and CEA001275) were packaged and shipped to the recipients. If your entity has determined that a failure to comply with all applicable laws concerning package and shipping as required under 42 C.F.R. Part § 73.16 has occurred, please provide a plan of how Lawrence Livermore National Laboratory will achieve compliance with 42 C.F.R. 73.

Please provide us in writing a response to this letter by close of business on September 29, 2005.

Please contact Lori Bane, Compliance Officer with the CDC Select Agent Program at (404) 498-2280 or at the address listed below if you have additional questions.

Charles Brokopp, DrPH
Director of Division of Select Agents and Toxins
Centers for Disease Control and Prevention
1600 Clifton Road N.E., MS E-79
Atlanta, GA 30333
Telephone: 404-498-2255; FAX: 404-498-2265

Recd 24 Jan 06

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30333

TO: Brynte Johnson, Responsible Official
Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, CA 94550
FAX: (925) 422-5176

FR: Centers for Disease Control and Prevention, Select Agent Program

DATE: November 16, 2005

RE: Facility Inspection Report: Lawrence Livermore National Laboratory

As a result of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have established requirements regarding possession, use, and transfer of select agents and toxins. These requirements were published in the Federal Register by HHS (42 CFR Part 73) and by USDA (7 CFR Part 331 and 9 CFR Part 121). CDC inspects entities to evaluate if they meet the requirements set forth in 42 CFR 73 ("Possession, Use and Transfer of Select Agents and Toxins; Final Rule"). The regulations and supporting information may be found at http://www.cdc.gov/od/sap/.

Inspectors from the CDC Select Agent Program visited your facility located at 7000 East Avenue, Livermore, CA 94550 on August 30, 2005. A list of the laboratories inspected on August 30, 2005 is on file with this letter at CDC. The following personnel from the CDC and APHIS Select Agent Programs inspected the facility:

James Blaine, Lead Inspector
Diane Martin, Inspector

Individuals from the Lawrence Livermore National Laboratory present during the inspection included:

Tricia Barbosa, Laboratory Safety Officer
Amit Basu,
Monica Borucki, Biomedical Scientist
Elbert Breusoug,
Alan Casamajor, Responsible Official (ARO)
Brett Chromy, Postdoc
Michel Dahlstrom, Security
Joseph Fitch, Program Leader Chem/Bio Nat'l Program
Glenn Funk, Alternate Responsible Official, Biosafety Officer (ARO)
Emilio Garcia, Senior Biomedical Scientist
Ann Holtz, Biomedical Scientist
Bill Hoppes,
Brynte Johnson, Alternate Responsible Official (RO)
James Johnson, Alternate Responsible Official (ARO)
Jim Marcisz, Laboratory Security Officer
Mary McBride, Biomedical Scientist
Sandra McCutchen-Maloney, Group Leader
Bruce McDowell, BSL-3 Program Manager
Lee McLemore,
Kris Montgomery,
Amy Rasley, Biomedical Scientist
Vin Taneja, Lab Audit Coordinator
Sarah Wenning,

Transfer documents (APHIS/CDC Form 2) were examined and departures from regulatory requirements were noted. The entity was questioned about the safety of the anticipated transfer of large quantities of select agents in one shipment and the inspectors were informed that precautions would be taken to prevent any safety hazard. Subsequent problems with the transfer of these select agents to another laboratory demonstrated that these precautions were not adequate and the procedures for shipping select agents from the entity need to be re-examined. There were no reports of select agents or toxins from clinical or diagnostic specimens (APHIS/CDC Form 4) to examine because the entity states they do not perform clinical or diagnostic work. During the same visit, however, departures from nationally recognized safety standards and/or deviations from requirements of 42 CFR 73 were noted. Please address each of the items described in Attachment 1 and include in your response the specific actions or changes you will adopt to correct these deficiencies. Provide a detailed response to this office within 30 calendar days of receipt of this letter. Failure to fully respond to this request may result in withdrawal of your facility registration for the possession, transfer or receipt of select agents.

If you have questions concerning this correspondence please contact James Blaine at 404-498-2255.

We appreciate your assistance during this inspection.

Sincerely,

Charles Brokopp, DrPH
Director, Select Agent Program
Office of Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention
1600 Clifton Road N.E., Mail Stop E-79
Atlanta, GA 30333
Telephone: (404) 498-2255; FAX: (404) 498-2265

Attachment:
List of Facility Departures

Attachment 1: Facility Departures

1 **Requirement:** Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory. [NIH, p. 70, Appendix G-II-B-2-a]

Observation: Waste from laboratory room 108 is transported in an open tray to the autoclave for decontamination. Please provide documentation that this departure has been addressed.

2 **Requirement:** An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security: (8) Separate areas where select agents and toxins are stored or used from the public areas of the building. [42 CFR § 73.11(d)(8)]

Observation: Contaminated materials containing select agents are transferred from laboratory 108 in building 364 and stored in room 101 until it can be autoclaved. Please provide the measures in place for assuring that this material is not removed by un-authorized individuals and for assuring that there is no risk of release of this material from containment.

3 **Requirement:** The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. [42 CFR § 73.11(f)]

Observation: Security plans are reviewed annually however there is no protocol in the security plan for conducting drills or exercises to test and evaluate the effectiveness of the plan. Please provide a copy of the section in the security plan that addresses this requirement.

4 **Requirement:** The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. [42 CFR § 73.12(d)]

Observation: There were no protocols for conducting drills or exercises to test and evaluate the effectiveness of the biosafety plan. Please provide a copy of the protocol that addresses this requirement.

5 **Requirement:** An individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator. [42 CFR § 73.13(a)]

Observation: Dr. Garcia is using knockout techniques which produce temporary antibiotic resistant Yersinia pestis. A request for review by the CDC Select Agent Program of this research should be submitted to confirm that this research presents no public health hazard.

6 **Requirement:** An individual or entity required to register under this part must develop and implement a written incident response plan. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review. [42 CFR § 73.14(a)]

Observation: No incident response plan for laboratories where select agents are used or stored was available for review at the time of the inspection. Please provide a copy of the entity incident response plan that addresses each of the requirements in 73.14.

7 **Requirement:** An individual or entity required to register under this part must provide information and training on biosafety and security to each individual with access approval from the HHS Secretary or Administrator before he/she has such access. In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access from the HHS Secretary or Administrator before he/she works in or visits areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. [42 CFR § 73.15(a)]

Attachment 1: Facility Departures

Observation: Not all individuals listed on section 4B with access to areas where select agents or toxins are used or stored have had safety training or biosecurity training that addressed the particular needs of the individual, the work they will do and the risks posed by the select agents or toxin. The following individuals did not have documentation of adequate training: Michael Boykin, Amie Brockmire, Randall Carter, Alan Casamajor, Megan Choi, Brett Chromy, Ann Clatworthy, Todd Corzett, Gordon Dakin, Michael Derksen, Jeffrey Elliott, Anne Erler, Lanette Fread, Glenn Funk, Emilio Garcia, Arturo Garjeda, Robert Garrett, Patsy Gilbert, Michelle Gookin, Sara Hall, Bonnie Heatherly, James Holderman, Ann Holtz, Richard Hulsebosch, Alfred Jin, Brynte Johnson, James Johnson, Gary Jones, Mark Kaufeldt, Victoria Lao, Christine Little, Keith Logan, Anthony Madrid, Edward Maldonado, Gary March, Cynthia Mariolle, Mary McBride, Summer McCloy, Sandra McCutchen-Maloney, Sharon Messenger, Nancy Montgomery, William Parsons, Rick Pavia, Lyndsay Radnedge, Brent Ricks, Kenneth Rinna, Anthony Salaices, Donald Schneider, Henry Schreiber, Saima SHams, David Shepard, Sean Sinclair, Kimothy Smith, Todd Stephens, Cheryl Strout, Lynn Suer, Rober Verdie, Kenneth Walden, Stephen Walker, David Wetherell, Celia Zhang. Please provide verification that this requirement has been addressed.

8 **Requirement:** Refresher training must be provided annually. [42 CFR § 73.15(b)]

Observation: The Responsible Official indicated that personnel working with select agents and toxins in laboratory rooms 108, 109, 111, and 112 received select agent training initially at start of work in those areas but did not receive refresher training annually. Please provide documentation that this requirement has been addressed.

9 **Requirement:** A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training. [42 CFR § 73.15(c)]

Observation: Not all individuals listed on section 4B with access to areas where select agents or toxins are used or stored have had safety training or biosecurity training that addressed the particular needs of the individual, the work they will do and the risks posed by the select agents or toxin. The following individuals did not have documentation of adequate training: Michael Boykin, Amie Brockmire, Randall Carter, Alan Casamajor, Megan Choi, Brett Chromy, Ann Clatworthy, Todd Corzett, Gordon Dakin, Michael Derksen, Jeffrey Elliott, Anne Erler, Lanette Fread, Glenn Funk, Emilio Garcia, Arturo Garjeda, Robert Garrett, Patsy Gilbert, Michelle Gookin, Sara Hall, Bonnie Heatherly, James Holderman, Ann Holtz, Richard Hulsebosch, Alfred Jin, Brynte Johnson, James Johnson, Gary Jones, Mark Kaufeldt, Victoria Lao, Christine Little, Keith Logan, Anthony Madrid, Edward Maldonado, Gary March, Cynthia Mariolle, Mary McBride, Summer McCloy, Sandra McCutchen-Maloney, Sharon Messenger, Nancy Montgomery, William Parsons, Rick Pavia, Lyndsay Radnedge, Brent Ricks, Kenneth Rinna, Anthony Salaices, Donald Schneider, Henry Schreiber, Saima SHams, David Shepard, Sean Sinclair, Kimothy Smith, Todd Stephens, Cheryl Strout, Lynn Suer, Rober Verdie, Kenneth Walden, Stephen Walker, David Wetherell, Celia Zhang. Please provide verification that this requirement has been addressed.

10 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: (1) Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including: (iv) When moved from storage and by whom and when returned to storage and by whom. [42 CFR § 73.17(a)(1)(iv)]

Observation: The freezer access log for laboratory room 111 is used to record movement of select agent from storage or to storage for the -80 freezer only. Laboratory workers indicated that select agents were also stored in other freezers in that room. Please provide documentation that addresses this requirement.

11 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: (1) Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including: (iv) When moved from storage and by whom and when returned to storage and by whom. [42 CFR § 73.17(a)(1)(iv)]

Attachment 1: Facility Departures

Observation: Inspectors noted that although laboratory workers discussed removal of select agent from the freezer located in room 109, this activity was not recorded on the freezer access log. Please provide verification that this requirement has been addressed.

12 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: (1) Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including: (iv) When moved from storage and by whom and when returned to storage and by whom. [42 CFR § 73.17(a)(1)(iv)]

Observation: There was no freezer access log kept for the select agents stored in laboratory room 108. Please provide documentation that this requirement has been addressed.

13 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: (1) Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including: (v) The select agent used and purpose of use. [42 CFR § 73.17(a)(1)(v)]

Observation: The freezer access log for laboratory room 111 records the select agent used but not purpose of use. Please provide documentation that addresses this requirement.

14 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: (1) Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including: (vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient. [42 CFR § 73.17(a)(1)(vii)]

Observation: At the time of the inspection the Responsible Official stated that Kimothy Smith, who was a PI at the entity, has since left the entity but the entity has not transferred the select agents under his control to an individual with authorization to possess these select agents and has not notified the Select Agent Program that Kimothy Smith is no longer with the entity. Please provide documentation that the agents have been destroyed or transferred to an authorized individual. Please also provide an amendment that removes Kimothy Smith from the list of entity personnel.

15 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: (3) A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator. [42 CFR § 73.17(a)(3)]

Observation: The entity has removed Bradley, Dichner, Linney, McLaughlin and Walker but they still have access to Bldg 365 according to the Argus printout of 1 September 2005. Please verify that these individuals access has been removed.

16 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: (4) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry. [42 CFR § 73.17(a)(4)]

Observation: Individuals recording access into laboratory room 111 used their initials, not their name to record access into the laboratory. Please provide verification that the name of the individual entering into areas containing select agents or toxins will be recorded.

17 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: (4) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry. [42 CFR § 73.17(a)(4)]

Attachment 1: Facility Departures

Observation: There are hard copy records of personnel entering the laboratories in Building 365 that contain ditto marks instead of names. This presents a problem in confirming that the individual accessing the room is authorized to do so. Please provide verification that personnel entering laboratories containing select agents are required to enter their full name.

18 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: (4) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry. [42 CFR § 73.17(a)(4)]

Observation: The access log for entry into laboratory room 108 does not record the name of the escort who is accompanying an unapproved individual. Please provide documentation that this requirement has been addressed.

19 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: (5) A written explanation of any discrepancies. [42 CFR § 73.17(a)(5)]

Observation: No protocols were found describing how an explanation of discrepancies, should they occur, will be recorded. Please provide a copy of the protocol that addresses this requirement.

20 **Requirement:** A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and follow instructions on practices and procedures. [BMBL, p.63, A(4)]

Observation: At the time of inspection, there were no animal care standard operating procedures for work in laboratory room 100 available for review. Please provide documentation that addresses this departure.

21 **Requirement:** Cages are washed in a cage washer. The mechanical cage washer has a final rinse temperature of at least 180° F. [BMBL, p.66, D(10)]

Observation: Verification that the final rinse temperature of the cage washer used to sanitize cages used in laboratory room 100 is at least 180 degrees F is by recording the temperature noted on the washer temperature gauge. Additionally, a mercury thermometer is used to manually check the temperature of the water leaving the cage washer on a weekly basis. Please provide verification that the recording devices used to ensure proper temperature has been reached are calibrated on a periodic basis and accurately recording final rinse temperature.

22 **Requirement:** A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Appropriate information to be posted includes the agent(s) in use, the biosafety level, the required immunizations, the investigator's name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory. [BMBL, p.21, B(3)]

Observation: The laboratory signage for rooms 108, 109, 111 and 112 did not include any requirements for immunization or any procedures required for exiting the laboratory.

23 **Requirement:** Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual adopted or prepared specifically for the laboratory by the laboratory director. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures. [BMBL, p.22, B(6)]

Observation: The biosafety manual for laboratories in building 365 did not include all of the agents currently listed on the certificate of registration. Please provide documentation that this departure has been addressed.

24 **Requirement:** Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated. [BMBL, p.25-26, D(6)]

Observation: The covering on one of the chairs in laboratory room 112 was ripped, exposing the foam padding. Please provide verification that this departure has been addressed.

25 **Requirement:** When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures. [BMBL, p.29, B(4)]

Observation: The entity was not able to provide the hazard warning signes that will be posted at the entrance of the laboratories when the laboratory becomes operational. Please provide a copy of the signs that will be posted and verification that the signs are posted prior to the building becoming operational.

26 **Requirement:** Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination with infectious materials. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted. [BMBL, p.31, B(12a)]

Observation: There are currently no spill procedures posted in any of the laboratories in building 368. Please provide a copy of the spill procedures that will be posted and verify that these procedures have been posted before the building becomes operational.

27 **Requirement:** Animals and plants not related to the work being conducted are not permitted in the laboratory. [BMBL, p.32, B(16); NIH, p.73, Appendix G-II-C-2-i]

Observation: Policies that restrict animals and plants not related to the work being conducted from the laboratories in building 368 and 365 were not found in the documentation presented to the inspectors. Please provide a copy of the documentation that address this safety standard.

28 **Requirement:** The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience. [BMBL, p.36, D(15)]

Observation: Adequate verification of facility design and operational procedures for the new BSL3 suite in building 368 was not provided to inspectors at the time of the inspection however documentation was forwarded after the inspection. The documentation provided was reviewed and the following problems were found: Rooms designed to be negative were showing a positive reading, there were decon room supply phoenix valve problems and leaking duct work. There was no indication in the documents provided that these problems had been addressed. Please provide the measures implemented to address these problems, the measures implemented to ensure that all standards are met before the laboratory becomes operational, and the measures implemented to monitor this laboratory to ensure that all standards are maintained.

29 **Requirement:** Persons under 16 years of age shall not enter the laboratory. [NIH, p.72, Appendix-G-II-C-1-g]

Observation: There is entity documentation that provides for allowing individuals under the age of 16 in the laboratories. Please provide an explaination for this exception to laboratory safety standards.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30333

TO: Brynte Johnson (Responsible Official)
Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, CA 94550
FAX: (925) 422-5176

FR: Centers for Disease Control and Prevention, Select Agent Program

DATE: March 29, 2006

RE: Notification of approval for registration under 42 CFR Part 73

Attached is the following:

(1) A registration certificate;
(2) A letter of explanation regarding registration of your entity with the CDC Select Agent Program; and
(3) A listing of individuals at your entity that you have identified as requiring a security risk assessment approval and the current status of their risk assessment approval.

Originals will follow by mail. Please contact your designated CDC representative at the CDC Select Agent Program if you have questions. If you are unsure who your designated CDC representative is, then please call 404-498-2255.

Sincerely,

Charles Brokopp

Charles Brokopp, DrPH
Director, Select Agent Program
Office of Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention
1600 Clifton Road N.E., Mail Stop E-79
Atlanta, GA 30333
Telephone: (404) 498-2255; FAX: (404) 498-2265

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

TO: Brynte Johnson, Responsible Official
Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, CA 94550
FAX: (925) 422-5176

FR: Centers for Disease Control and Prevention, Select Agent Program

DATE: March 29, 2006

RE: Notification of approval for registration under 42 CFR Part 73

Your registration certificate is attached with this letter. The entity registration is valid only for the select agents and toxins listed, the specified activities at the locations described in your application, and for the conditions that were approved under 42 CFR Part 73, 7 CFR Part 331, or 9 CFR Part 121, to possess, use, or transfer select agents or toxins. The registration certificate does not confer approval for pending amendment requests or supersede any correspondence that may be related to compliance or other pending issues at your entity. Your registration number should be referenced on all correspondence and select agent forms submitted to this program.

Based on the observations noted during the inspection of your entity on February 28, 2006 for the review of the changes implemented by Lawrence Livermore National Laboratory, the Centers for Disease Control and Prevention (CDC), Select Agent Program has rescinded its decision dated September 22, 2005 which stated that the CDC Select Agent Program would not approve transfer requests received from Lawrence Livermore National Laboratory. Please be reminded that a select agent or toxin may only be transferred under the conditions described in 42 CFR § 73.16 and must be authorized by CDC or APHIS prior to the transfer (see 42 CFR § 73.16(a)).

A list of all personnel at your entity that you have identified as requiring a security risk assessment approval and the current status of their security risk assessment is provided in an attachment to this letter. The list also includes each individual's unique DOJ identifying number that should used with any further communications regarding the specific individuals. Individuals not appearing on the enclosed list as SRA approved or not appearing on the list must be denied access to select agents or toxins by the Responsible Official and Alternate Responsible Official(s).

Please contact your designated CDC representative if you have questions. If you are unsure who your designated CDC representative is, then please call 404-498-2255.

Charles Brokopp

Charles Brokopp, DrPH
Director of Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Road N.E., MS E-79
Atlanta, GA 30333
Telephone: 404-498-2255; FAX: 404-498-2265

(a) "SRA Approved" = granted a security risk assessment approval.
(b) "Restricted" = denied access to select agents or toxins because the United States Attorney General has determined the individual has met the restricted person definition. Be reminded that it is the Responsible Official's responsibility to deny access to any select agent or toxin to an individual identified by the United States Attorney General as being a restricted person as defined by 18 U.S.C. 175b (42 C.F.R. 73.8(e)).
(c) "Denied" = denied access to select agents or toxins because CJIS reported that they had not received a FD-961 form or fingerprint cards as required to conduct a security risk assessment.
(d) "Canceled" = denied access to select agents or toxins because the entity has determined that the individual does not need a security risk assessment because they are not the Responsible Official, owner or controller of the entity, or an individual that will have access to select agents or toxins.

Certificate of Registration

Entity Name: Lawrence Livermore National Laboratory
Address: 7000 East Avenue,
Livermore, CA 94550

Registration #: C70060320-0442
Effective Date: March 29, 2006
Expiration Date: March 13, 2009

Responsible Official: Bruce Johnson
Alternate Responsible Official(s): Alan Casamajor, Alfred Jin, James Johnson

Based on information provided to the CDC Select Agent Program and the APHIS/Agriculture Select Agent Programs, the above-named entity is authorized to possess, use, and transfer select agents and toxins under the conditions specified in the entity registration application, in accordance with 42 CFR part 73, 9 CFR part 121, and 7 CFR part 331.

Charles Brokopp, Director
Select Agent Program
Centers for Disease Control and Prevention

Lee Ann Thomas, Director
Select Agent Program
Veterinary Services

Michael J. Firko, Director
Biological and Technical Services
Plant Protection and Quarantine

CDC

APHIS

NA--LSO-LLNL-LLNL-2005-0078

FINAL

Occurrence Report
After 2003 Redesign

Lawrence Livermore Nat. Lab. (BOP)

(Name of Facility)

Laboratory - Research & Development

(Facility Function)

Lawrence Livermore National Lab.

(Site)

Lawrence Livermore National Lab.

(Contractor)

Name: Jim Merrigan
Title: SEP Assurance Manager

Telephone No.: (925) 424-6983

(Facility Manager/Designee)

Name: ECCHER, BARBARA A
Title: OCCURRENCE REPORTING OFFICER

Telephone No.: (925) 422-9332

(Originator/Transmitter)

Name: na

Date: 10/04/2006

(Authorized Classifier (AC))

1. Occurrence Report Number: NA--LSO-LLNL-LLNL-2005-0078
Previous OR # NA-OAK--LLNL-LLNL-2005-0078

Select Agent Shipping

2. Report Type and Date: FINAL

	Date	Time
Notification:	09/23/2005	22:37 (ETZ)
Initial Update:	09/26/2005	15:53 (ETZ)
Latest Update:	09/12/2006	13:05 (ETZ)
Final:	09/12/2006	13:05 (ETZ)

3. Significance Category: 3

4. Division or Project: SEP

5. Secretarial Office: NA - National Nuclear Security Administration

6. System, Bldg., or Equipment: 365

7. UCNI?: No

8. Plant Area: Site 200-Biosciences

9. Date and Time Discovered: 09/23/2005 16:30 (PTZ)

10. Date and Time Categorized: 09/23/2005 18:30 (PTZ)

11. DOE HQ OC Notification:

Date	Time	Person Notified	Organization
NA	NA	NA	NA

12. Other Notifications:

Date	Time	Person Notified	Organization
09/23/2005	19:15 (PTZ)	Kearns	NNSA/LSO

13. Subject or Title of Occurrence:

Select Agent Shipping

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14. Reporting Criteria:

8(2) - Any offsite transport of hazardous material, including radioactive material, whose quantity or nature (e.g., physical or chemical composition) is different than intended, such that the receiving organization's operations were impacted/disrupted or the transport resulted in the initiation of corrective actions by the originating organization.

9(2) - Any written notification from an outside regulatory agency that a site/facility is considered to be in noncompliance with a schedule or requirement (e.g., Notice of Violation, Notice of Intent to Sue, Notice of Noncompliance, Warning Letter, Finding of Violation, Finding of Alleged Violation, Administrative Order, or a similar type of notification or enforcement action).

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15. Description of Occurrence:

On September 22, 2006, LLNL received a letter from the Centers for Disease Control and Prevention (CDC) stating that it would not approve future requests from LLNL to transfer select agents. This condition was based on a CDC determination of a need to investigate allegations that LLNL may have failed to comply with applicable laws regarding packaging and shipping of Select Agents (pathogenic materials). In March 2006, the CDC rescinded it's September 22, 2005 decision. A letter dated March 29, 2006, to LLNL from the CDC stated:

"Based on the observations noted during the inspection of your entity on February 28, 2006, for the review of the changes implemented by Lawrence Livermore National Laboratory, the CDC, Select Agent Program, has rescinded its decision dated September 22, 2005, which stated that the CDC Select Agent Program would not approve transfer requests received from Lawrence Livermore National Laboratory."

In addition, the CDC issued LLNL a registration certificate under 42 CFR Part 73, which is valid for a listed set of select agents and toxins. The certificate defines conditions for the possession, use, or transfer of the listed select agents and toxins.

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16. Is Subcontractor Involved? No

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17. Operating Conditions of Facility at Time of Occurrence:

normal

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18. Activity Category:

08B - Transportation Offsite

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19. Immediate Actions Taken and Results:

All shipments of select agents to and from LLNL were suspended.

An LLNL incident analysis team was formed and an analysis was conducted.

In March 2006, the Centers for Disease Control and Prevention, Select Agent Program, rescinded its decision to not approve transfer requests received from LLNL and it issued a certificate of registration to the Laboratory.

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20. ISM:

1) Define the Scope of Work
2) Analyze the Hazards
3) Develop and Implement Hazard Controls
4) Perform Work Within Controls

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21. Cause Code(s):

A4B3C09 - Management Problem; Work Organization & Planning LTA; Work planning not coordinated with all departments involved in task
A4B4C06 - Management Problem; Supervisory Methods LTA; Job performance and self-checking standards not properly communicated

A4B3C08 - Management Problem; Work Organization & Planning LTA; Job scoping did not identify special circumstances and/or conditions
A3B1C04 - Human Performance Less Than Adequate (LTA); Skill Based Errors; Infrequently performed steps are performed incorrectly
-->couplet - A4B1C03 - Management Problem; Management Methods Less Than Adequate (LTA); Management direction created insufficient awareness of the impact of actions on safety / reliability
A5B4C01 - Communications Less Than Adequate (LTA); Verbal Communications LTA; Communication between work groups LTA
A4B4C01 - Management Problem; Supervisory Methods LTA; Tasks and individual accountability not made clear to worker

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22. Description of Cause:

A4B3C09 Work planning not coordinated with all departments involved with task. Oversight by LLNL Bioscience's line management chain of overall planning and execution was less than adequate. There was no pre-start review or official planning with participation of all the parties involved. [LLNL IA518-C, JON 1]

A4B4C06 Job performance and self-checking standards not properly communicated. Neither the LLNL Responsible Official, nor the Alternate ensured that packaging and shipping regulatory requirements (CDC) were met. They did not follow LLNL's Environment, Safety, and Health Manual or Integration Work Statement 10411.01 requirements for ensuring the proper packaging and shipping of hazardous materials (select agents). In addition, the LLNL Responsible Official did not know the DOT/IATA requirements for packaging and shipping, and and the Alternate did not check the CDC Form 2 (section D) for all the signatures before it was placed into the packaging. [LLNL IA518-C, JON 2, 3, 4, and 5]

A4B4C01 Tasks and individual accountability not made clear to worker
Delegation and understanding of roles and responsibilities of the parties involved (Responsible Official, Responsible Individual, Bio-Safety Officer, Alternate Bio-Safety Officers, and Visitor) were less than adequate. LLNL has not formalized the full complement of the Responsible Official's institutional responsibilities (e.g., position description). LLNL management has not clearly defined the Responsible Official's roles and responsibilities internal to the Laboratory, so that skills, knowledge, and abilities could be determined for the Responsible Official position. [LLNL IA518-C, JON 6 and 7]

A3B1C04 Infrequently performed steps were performed incorrectly and A4B1C03 Management direction created insufficient awareness of impact of actions on safety/reliability. Adherence to the Integrated Safety Management and Integrated Safeguards and Security Management processes and to Integration Work Sheet 10411.01 were less than adequate. The Integration Work Sheet 10411.01, referenced documents (Environment, Safety, and Health Manual documents 21.1 and 13.1, Facility Safety Plan 360, and Standard Operations Procedure BCF-B365-111/112-0007 and 200.20), and the Bio-security plans (Institutional and Building 365) were not followed by the personnel involved in this activity. [LLNL IA518-C, JON 8]

A4B3C08 Job scoping did not identify special circumstances and/or conditions. Process for the checkout and termination from LLNL for the custodianship of record with the CDC was less than adequate. No formal mechanisms exist to ensure that LLNL's requirements to transfer custodianship of select agents occurred when employees terminate from LLNL. Select-agent inventory process and system was less than adequate. There was no robust, automated inventory management system for select agents. [LLNL IA518-C, JON 9 and 10]

A5B4C01 Lack of communication w/support groups contributed to the incident. The owner of the select agent collection did not transfer responsibility for the collection to another responsible individual or package the collection for transport prior to terminating as an employee and leaving LLNL. The personnel designated to package and arrange transport of the collection failed to follow written policies and procedures for such work and they did not conduct a review of the work to be performed with ES&H technical expert support personnel. [LLNL IA518-C, JON 11]

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23. Evaluation (by Facility Manager/Designee):

Failure to follow written procedures for select-agent packaging and shipping negatively affected the Laboratory ability to complete its mission activities for a short period until adequate controls were in place. Corrective actions by the Laboratory will prevent a recurrence of the occurrence. Operations have returned to normal.

Note:

6/16/06 Update: Change organizational ownership from DO to SEP.

Assigned Incident Analysis(#0518).

OR LLNL 2005-0077 was be cancelled and replaced by this more comprehensive OR.

The DOE FR was contacted to discuss issues regarding the time line of this report.

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24. Is Further Evaluation Required?: No

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25. Corrective Actions

(* = Date added/revised since final report was approved.)

1. JON 1.1 Biosciences will review all IWSs involving select agent work and verify that the Responsible individual and alternate Responsible individual are appropriately trained and that they have management's confidence to execute Select Agent work Cause-A4B3C09

Target Completion Date: 04/30/2006	**Completion Date:** 02/27/2006

2. JON 1.2 The Select Agent Center Manager, with assistance from subject matter experts from the Hazards Control and Security Departments, will conduct a briefing on Work Activity Level-C pre-start reviews to ensure the Authorizing Individuals, Responsible Individuals and alternate Responsible Individuals understand how to conduct a pre-start review and their roles and responsibilities. Cause-A4B3C09

Target Completion Date: 04/30/2006	**Completion Date:** 02/27/2006

3. JON 1.3 For any new work the Select Agent Center Manager will review the selection and training of the Responsible Individual and alternate Responsible Individual and ensure requirements of safety and security are met. Cause-A4B3C09

Target Completion Date: 04/30/2006	**Completion Date:** 02/27/2006

4. JON 1.4 NAI, BIO, and SEP Associate Directors will present a Select Agent Management Proposal to the Deputy Director for Operations. The management plan will outline the roles and responsibilities of the line management in the execution of select agent work at the LLNL. Cause-A4B3C09

Target Completion Date: 01/05/2006	**Completion Date:** 01/03/2006

5. JON 2 The Responsible Official and Alternate Responsible Officials will perform the necessary training to become sufficiently competent to receive DOT/IATA certification Cause-A4B4C06

Target Completion Date: 04/30/2006	**Completion Date:** 02/27/2006

6. JON 3 The Safety and Environmental Protection Associate Director and Hazards Control Department Head will evaluate the understanding of the Responsible Official, alternate Responsible Officials, and Packaging and Transportation Safety Program Leader regarding the fact that LLNL is responsible for Select Agents, regardless of perceived ownership, and will make needed adjustments to assure this issue is well understood. Cause-A4B4C06

Target Completion Date: 02/28/2006	**Completion Date:** 02/03/2006

7. JON 4 The SEP Associate Director and Hazards Control Department Head will evaluate the understanding of the Responsible Official, alternate Responsible Officials, and Packaging and Transportation Safety Program Leader regarding the fact that LLNL is responsible for proper packaging and shipping of LLNL's Select Agents, and will make needed adjustments to assure this issue is well understood. Cause-A4B4C06

Target Completion Date: 02/28/2006	**Completion Date:** 02/03/2006

8. JON 5 The RO and Packaging and Transportation Safety Program Leader will develop a procedure for completion of forms needed for Select Agent shipments that will include a process for adequate review of the forms for accuracy and completeness. Cause-A4B4C06

Target Completion Date: 05/15/2006	**Completion Date:** 05/12/2006

9. JON 6.1 Select Agent information will be removed from Environment, Safety, and Health Manual Document 13.1 and will be incorporated into a new Environment, Safety, and Health Manual Document 13.7, which will address management of Select Agents and will assure the roles and responsibilities for the Responsible Official position and the Bio-safety Officer are clear and have no conflicts. Hazards Control Department's Safety Program Leader will review the document change to assure the concerns in the Incident Analysis are addressed. Cause-A4B4C01 In the interim the Laboratory relies on existing documents and completed actions to address roles and responsibilities and for management of Select Agents. The Centers for Disease Control and Prevention has rescinded its decision to not approve transfer requests received from LLNL and has issued a certificate of registration to the Laboratory.

Target Completion Date: 12/31/2006	**Completion Date:** 12/21/2006

10. JON 6.2 New Environment, Safety, and Health Manual Document 13.7 will be approved by the ES&H Working Group. Cause-A4B4C01

Target Completion Date: *07/31/2007	**Completion Date:** 06/18/2007

11. JON 6.3 The Deputy Director for Operations will approve new Environment, Safety, and Health Manual Document 13.7. Cause-A4B4C01

Target Completion Date: *08/31/2007	**Completion Date:** 06/28/2007

12.	JON 6.4 The Safety and Environmental Protection Directorate will issue a formal delegation letter to individuals in Responsible Official and alternate Responsible Official assignments. Cause-A4B4C01	
	Target Completion Date: 02/28/2006	**Completion Date:** 02/07/2006
13.	JON 7 Formal position descriptions, including Skills, Knowledge, and Abilities, will be developed for the Bio-Safety Officer, alternate Bio-Safety Officer, Responsible Official and alternate Responsible Officials. The Deputy Director for Operations will concur with all Responsible Official and alternate Responsible Official position descriptions. Cause-A4B4C01	
	Target Completion Date: 02/28/2006	**Completion Date:** 02/27/2006
14.	JON 8.1 The Select Agent Center Manager will assure that pre-start review training will include review of all applicable controlling documents for Select Agent work. Cause-A3B1C04 and A4B1C03	
	Target Completion Date: 04/30/2006	**Completion Date:** 02/28/2006
15.	JON 8.2 Upgrade the annual bio-security training to incorporate lessons learned from this event. The bio-security training materials will be updated to include: JON 1 Emphasize the types of concerns that should be reported, and provide specific learning examples to demonstrate the lessons learned from this event. JON 3 Emphasize that LLNL is the owner entity of any Select Agent materials shipped from this site. JON 8 Emphasize the importance of security in all activities, especially in the pre-start review WAL C of Select Agent work. JON 9 Emphasize that at any time there is an issue, concern or discrepancy with inventory the Security Department is notified. JON 11 Emphasize that only approved authorized individuals are allowed to handle Select Agents. Cause-A3B1C04 and A4B1C03	
	Target Completion Date: 02/28/2006	**Completion Date:** 02/28/2006
16.	JON 9 Develop a Lab-wide electronic inventory system that ties Select Agent ownership to employees. Cause-A4B3C08 The Laboratory currently uses an interim inventory system and the Centers for Disease Control and Prevention has rescinded its decision to not approve transfer requests received from LLNL and has issued a certificate of registration to the Laboratory	
	Target Completion Date: 09/30/2006	**Completion Date:** 09/30/2006
17.	JON 10 Identify and implement an automated inventory management system appropriate for Select Agents. Cause-A4B3C08 The Laboratory is operating an interim inventory system and the Centers for Disease Control and Prevention has rescinded its decision to not approve transfer requests received from LLNL and has issued a certificate of registration to the Laboratory.	
	Target Completion Date: 09/30/2006	**Completion Date:** 09/30/2006
18.	JON 11 The Select Agent Center Manager will review all Standard Operations Procedures and reinforce with all staff working in the Select Agent Center laboratories, including the Responsible Official and alternate Responsible Officials, that only LLNL employees who are Security Risk Assessment approved will package Select Agents, and that only the LLNL Shipping Department is allowed to ship such materials. Cause-A5B4C01	
	Target Completion Date: 04/30/2006	**Completion Date:** 02/27/2006
19.	OMC 1 Define the Select Agent Center management chain and process to follow to ensure the correct organizations are informed of any incidents or departures that occur within the Select Agent Center. CauseA5B3C09	

Target Completion Date: 04/30/2006	**Completion Date:** 02/27/2006

20. OMC 2 The Responsible Official RO and the Select Agent Center Manager will review Standard Operating Procedure for removal and/or disposal of select agents with all Authorizing Individuals, Responsible Individuals and workers in B365 and B368. Cause-A5B4C06

Target Completion Date: 04/30/2006	**Completion Date:** 02/14/2006

21. OMC 3 Chem/Bio Nuclear Program programmatic Principal Investigators or Associate Program Leaders, who accept temporary assignment away from the LLNL site, will relinquish functional project supervision and Integration Work Sheet roles to on-site staff, named by the Program Leader, during the duration of the off-site assignment. Chem/Bio Nuclear Program management will consider any potential off-site assignments in naming future Principal Investigators or Associate Program Leaders assignments that may impact the Integration Work Sheet approval chain. The Select Agent Center management plan will address Integration Work Sheet roles and responsibilities and reporting lines. Cause-A5B3C08

Target Completion Date: 01/31/2006	**Completion Date:** 01/31/2006

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26. Lessons Learned:

Written roles and responsibilities remove the potential for confusion and lack of understanding which led to this event. Program participants were confused about who had responsibility to ensure the appropriate packaging of select agents and that confusion allowed this incident to occur. Written roles and responsibilities will be used for transportation of select agents.

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27. Similar Occurrence Report Numbers:

NA

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28. User-defined Field #1:

No Injury

29. User-defined Field #2:

No Property Damage

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30. HQ Keyword(s):

01A--Inadequate Conduct of Operations - Inadequate Conduct of Operations (miscellaneous)
01E--Inadequate Conduct of Operations - Operations Procedure Noncompliance
01F--Inadequate Conduct of Operations - Training Deficiency
01G--Inadequate Conduct of Operations - Inadequate Procedure
01N--Inadequate Conduct of Operations - Inadequate Job Planning (Other)
01P--Inadequate Conduct of Operations - Inadequate Oral Communication
01Q--Inadequate Conduct of Operations - Personnel error

01R--Inadequate Conduct of Operations - Management issues
10A--Transportation - Shipping Regulation Noncompliance
10D--Transportation - Notice of Violation or Noncompliance from local, state or federal agency
12P--EH Categories - Shipping QA

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31. HQ Summary:

Officials from the Center for Disease Control and Prevention, Select Agent Program, notified the Laboratory that they are investigating allegations that the Laboratory failed to comply with all applicable laws regarding packaging/shipping of Select Agent (pathogenic) materials. Subsequently, all shipments of select agents to/from the Laboratory were suspended, pending an independent investigation. Note: Based on further evaluation, this occurrence report cancels and replaces OAK-LLNL-LLNL-2005-0077 with a more comprehensive occurrence report.

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32. DOE Facility Representative Input:

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33. DOE Program Manager Input:

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34. Approvals:

Approved by: Jim Merrigan, Facility Manager/Designee
Date: 09/12/2006
Telephone No.: (925) 424-6983

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General
Washington, D.C. 20201

JAN 0 9 2007

RECEIVED
by
DIRECTOR'S OFFICE
2007 JAN 17 P 1:40

George H. Miller, Ph.D.
Director
Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, CA 94550

Dear Dr. Miller:

This letter is to advise you that the Office of Inspector General (OIG) for the United States Department of Health and Human Services has preliminarily determined that Lawrence Livermore National Laboratory (LLNL) may have violated the Select Agent regulations, 42 C.F.R. Part 73, in connection with transfers of the select agent *Bacillus anthracis* (anthrax) to Midwest Regional Institute-Florida Division (MRI) and American Type Culture Collection (ATCC).

Failure to Comply with Security and Access Requirements

The OIG believes that LLNL failed to comply with the Select Agent regulations' security and access requirements when it provided an unauthorized individual access to more than 4,000 vials of anthrax in September 2005. The Select Agent regulations provide that a registered entity may not provide an individual access to a select agent unless that individual has been approved by the Secretary of Health and Human Services (HHS Secretary), following a security risk assessment by the Attorney General. 42 C.F.R. § 73.10(a); 42 C.F.R. § 73.11(d)(1). We have determined that in September 2005, LLNL provided Pamela Coker, Ph.D. access to more than 5,000 vials of anthrax when she packaged LLNL's anthrax shipments for transfer to MRI and ATCC. The HHS Secretary had not approved Dr. Coker for access to a select agent at that time. Consequently, by providing Dr. Coker access to anthrax to ship to MRI and ATCC, LLNL provided an unauthorized individual access to a select agent. Therefore, LLNL may have violated the security and access requirements of sections 73.10(a) and 73.11(d)(1) of the Select Agent regulations.

Failure to Comply with Applicable Packaging and Shipping Laws

The OIG also believes that LLNL failed to comply with the Select Agent regulations packaging and shipping requirements. Select Agent regulations provide that an entity

must comply with all applicable laws concerning packaging and shipping when transferring a select agent. See 42 C.F.R. § 73.16(i). The Department of Transportation (DOT) Hazardous Materials Regulations, 49 C.F.R. Parts 171-180, set forth the shipping and packaging requirements for the commercial transport of hazardous materials, including anthrax. Those regulations provide, in pertinent part, that:

1) a shipper may only transport anthrax in a packaging or container that is an authorized package and is properly assembled, see 49 C.F.R. § 173.22(a)(2);

2) the inner packagings of combination packaging must be packed, secured, and cushioned so as to prevent breakage or leakage and to control the movement of the inner packagings under conditions normally incident to transportation, see 49 C.F.R. § 173.24a(a)(3);

3) the packaging of anthrax must be triple packaging consisting of, among other requirements, a watertight secondary packaging, see 49 C.F.R. § 173.196(a)(2). Multiple fragile primary receptacles placed in a single secondary packaging must be individually wrapped to prevent contact between them, id.;

4) infectious substances, such as anthrax, must be packaged with a positive means of ensuring a leakproof seal is provided, such as a heat seal, skirted stopper, or metal crimp seal, see 49 C.F.R. § 173.196(b)(2)(1);

5) non-bulk packaging must be marked with the proper shipping name and identification number, see 49 C.F.R. § 172.301(a); and

6) shipping papers listing anthrax are required to contain a 24 hour emergency response telephone number for use in the event of an emergency involving the anthrax, see 49 C.F.R. § 172.604(a). The telephone number must be the number of the person offering the material or an organization capable of providing detailed information concerning the hazardous material, see 49 C.F.R. § 172.604(b).

In September 2005, LLNL transferred shipments of more than 3,000 vials of anthrax to ATCC and more than 2,000 vials of anthrax to MRI. An investigation of the packaging for the shipments revealed the following: (1) certain vials were not properly secured and their caps were off or loose, resulting in the contents of the vials leaking; (2) the vials were not placed in appropriate packaging to prevent contact with one another, and the

loose arrangement resulted in jostling of the contents during shipping; (3) no absorbent material was placed between the vials and the secondary packaging; (4) multiple secondary cans were placed inside a box certified for one can; and (5) improper metal paint-type cans with pressure fitting lids were used instead of the DOT-approved container. Thus, the inner packaging of these shipments violated the DOT packaging requirements. See 49 C.F.R. §§ 173.22(a)(2), 173.24a(a)(3), 173.196(a)(2), 173.196(b)(2)(1). In addition, the packages did not have the proper shipping name, UN identification number, and Infectious Substance label as required by DOT shipping regulations. See 49 C.F.R. § 173.301(a). Finally, the packaging did not list the emergency response number of a person or organization capable of providing detailed information concerning the vials of anthrax, as required by DOT shipping regulations. See 49 C.F.R. § 172.604(b). Consequently, LLNL violated section 73.16(i) of the Select Agent regulations because it failed to comply with the packaging and shipping requirements of the DOT regulations when it transferred vials of anthrax to ATCC and MRI.

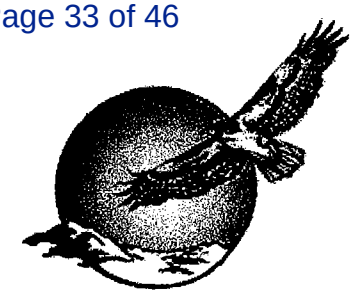
We are writing to extend to you the opportunity to provide us with additional information regarding these apparent violations. If you wish to submit additional information, please do so by February 9, 2007. You may provide the information to the attention of Senior Counsel Maame Gyamfi at the following address:

Department of Health and Human Services
Office of Inspector General
Office of Counsel to the Inspector General
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, D.C. 20201
(202) 205-9493

Sincerely,

Maame Gyamfi
Senior Counsel

Tri-Valley CAREs
Communities Against a Radioactive Environment
2582 Old First Street, Livermore, CA 94551 • (925) 443-7148 • Fax (925) 443-0177



Peace Justice Environment since 1983

September 19, 2007

Samuel Brinker
National Environmental Policy Act Document Manager
U.S. Department of Energy
National Nuclear Security Administration
Livermore Site Office, M/S L-293
P.O. Box 808
Livermore, CA 94551-0808
samuel.brinker@oak.doe.gov

Re: Biosafety Level 3 Facility at the Department of Energy's Lawrence Livermore National Laboratory Main Site

Dear Mr. Brinker:

Tri-Valley CAREs is a non-profit organization founded in 1983 by Livermore area residents to research and conduct public education and advocacy regarding the potential environmental, health, and proliferation impacts of the Department of Energy's (DOE) Lawrence Livermore National Laboratory (LLNL).

On behalf of our 5,600 members, Tri-Valley CAREs would like to reiterate its position that the National Environmental Policy Act (NEPA) requires the DOE to prepare an Environmental Impact Statement (EIS) for the proposed construction and operation of a Biosafety Level 3 (BSL-3) facility at LLNL. However, should the Department instead choose to issue a Finding of No Significant Impact (FONSI) for the proposed facility, we want to point out that DOE regulations under NEPA require the Department to issue a *proposed* FONSI for public review and comment prior to making a final determination on the FONSI. Finally, we would like to formally request that a public hearing be held on the proposed BSL-3 facility so that the public's concerns regarding the adequacy of the safety regulations for the biowarfare agent research facility may be addressed.

LLNL's unfortunate safety record and the potential for significant casualties following an accident or terrorist attack at the proposed BSL-3 facility highlight the need for further study and review. According to DOE documents, the BSL-3 facility at LLNL may place up to 1 liter quantities of live anthrax, plague, and numerous other deadly pathogens at risk.[1] Among other incidents, LLNL sent shipments of vials containing select agent material to two offsite

[1] Department of Energy, Draft Revised Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California 52 (2007).

laboratories in September 2005.[2] Upon receipt of the shipments, "it was determined that the inner packaging of these shipments violated [Department of Transportation (DOT)] packaging requirements and that the labels were missing important information."[3] As a result, all select agent work at LLNL was suspended, and the incident was examined by the Centers for Disease Control and Prevention (CDC) and the DOT.[4] The CDC subsequently produced a report that identified "29 points" that needed to be addressed before select agent work could be resumed at LLNL.[5] Also, it was determined that LLNL mistakenly conducted experiments with a potentially virulent strain of Bacillus anthracis in 1999 and improperly disposed of hypodermic needles, which resulted in a technician being stuck in the arm.[6]

An independent scientific analysis using a computer model distributed by an agency of the Department of Defense determined that "even in a lightly-damaged facility containing a small quantity of Anthrax[,] . . . the release of the agent [from the proposed facility] can, with certain prevailing winds, cause mass casualties."[7] Given the poor safety record at LLNL and the significant threat to public health and safety the proposed BSL-3 facility represents, a greater level of public involvement and the preparation of an EIS are essential to ensuring that the facility does not unnecessarily endanger workers and the surrounding communities.

The Proposed Construction and Operation of a Biosafety Level 3 Facility at LLNL Requires the Preparation of an EIS

The proposed BSL-3 facility at LLNL is a "major Federal action[] significantly affecting the quality of the human environment, [for which] a detailed statement [on] . . . the environmental impact of the proposed action" is required.[8] In *Tri-Valley CAREs v. Department of Energy*, the U.S. Court of Appeals for the Ninth Circuit ordered "the DOE to consider whether the threat of terrorist activity necessitates the preparation of an Environmental Impact Statement" for the proposed BSL-3 laboratory at LLNL.[9] As a result, the Department prepared a draft revised Environmental Assessment (EA) for the proposed BSL-3 facility "to consider the potential impacts of terrorist activity."[10] Although the DOE concluded in its *draft* document "that the potential for terrorist activity targeting the proposed BSL-3 facility does not result in measurable impacts to human health or the environment," this conclusion was not the result of the Department taking "a 'hard look' at the environmental consequences" of the proposed action.[11] On the contrary, the draft revised EA contains little new or substantive analysis and instead reflects the persistent intransigence of the DOE with regard to the preparation of an EIS

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[2] *Id.* at 57.
[3] *Id.*
[4] Lawrence Livermore National Laboratory Institutional Biosafety Committee, IBC Meeting Minutes 5 (November 16, 2005); Department of Energy, *supra* note 1, at 57.
[5] Department of Energy, *supra* note 1, at 57.
[6] Declaration of Marylia Kelley In Support of Plaintiffs' Motion for Summary Judgment at 6-7, Tri-Valley CAREs v. DOE, No. C-03-3926 (N.D.CA 2004).
[7] Declaration of Matthew G. McKinzie In Support of Plaintiffs' Motion for Summary Judgment at 6, Tri-Valley CAREs v. DOE, No. C-03-3926 (N.D.CA 2004).
[8] 42 U.S.C. § 4332(C) (1975).
[9] No. 04-17232, slip op. at 4 (9th Cir. 2006).
[10] Department of Energy, *supra* note 1, Forward at iii.
[11] *Id.* at 66; Muckleshoot Indian Tribe v. United States Forest Serv., 177 F.3d 800, 814 (9th Cir. 1999) (quoting Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989)).

for the BSL-3 facility. Accordingly, the Department should prepare an EIS for the proposed BSL-3 facility at LLNL that adequately addresses the environmental impacts of attacks or sabotage on the proposed biowarfare agent research facility and evaluates the comparative costs and benefits of a range of alternatives to avoid or mitigate those impacts.

If a FONSI Is Issued, DOE Regulations under NEPA Require the Department to Issue a Proposed FONSI for Public Review and Comment Prior to Making a Final Determination on the FONSI

If the DOE chooses to ignore the above considerations and instead issues a FONSI for the proposed BSL-3 facility at LLNL, pursuant to the Department's Implementing Procedures under NEPA, "DOE *shall* issue a proposed FONSI for public review and comment before making a final determination on the FONSI . . . ."[12] A public review and comment period is required in two situations: (i) where "[t]he proposed action is, or is closely similar to, one which normally requires the preparation of an environmental impact statement under the procedures adopted by the agency . . . or (ii) [where t]he nature of the proposed action is one without precedent."[13]

Let's take the two situations in order:

With regard to the first situation, in which a public review and comment period is required where the proposed action is, or is closely similar to, one which normally requires the preparation of an EIS under the procedures adopted by the DOE, the classes of actions that normally require the preparation of an EIS under the Department's Implementing Procedures all deal with energy and/or nuclear issues.[14] As such, the proposed BSL-3 facility is not among those classes of actions that normally require the preparation of an EIS under the DOE's regulations.[15] However, given that the Department "does not currently operate any microbiological laboratory facility above Biosafety Level 2 (BSL-2)," this is not surprising.[16]

Moreover, under similar circumstances, the Department has determined that "preparation of an EIS is the appropriate level of NEPA analysis for the operation of the BSL-3" laboratory at Los Alamos National Laboratory (LANL) in Los Alamos, New Mexico.[17] The issues to be analyzed in the LANL EIS include "[a]dditional seismic analysis; safety of laboratory operations; public health and safety; handling, collection, treatment, and disposal of research wastes; other risks; pollution prevention; and potential impacts on air quality, biological resources, cultural resources, water resources, land use, and socioeconomic resources."[18] Given the unique status of both LLNL and LANL as the nation's classified nuclear weapons design laboratories, there is no rational basis for preparing an EIS for the operation of the BSL-3 facility at Los Alamos and not Lawrence Livermore; the same issues which necessitated the preparation of an EIS for the LANL BSL-3 facility are equally applicable to the LLNL BSL-3 facility, if not

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[12] 10 C.F.R. § 1021.322(d) (1996) (emphasis added).
[13] 40 C.F.R. § 1501.4(e)(2) (1978).
[14] *See* 10 C.F.R. app. D to Subpart D to Part 1021 (1996).
[15] *Id.*
[16] Department of Energy, *supra* note 1, Executive Summary at iii.
[17] Notice of Intent To Prepare an Environmental Impact Statement for the Operation of a Biosafety Level 3 Facility at Los Alamos National Laboratory, Los Alamos, NM, 70 Fed. Reg. 71490 (Nov. 29, 2005).
[18] *Id.*

more so. For instance, "NNSA determined that it was necessary to conduct additional seismic analysis" concerning the Los Alamos BSL-3 laboratory and not the Lawrence Livermore BSL-3 laboratory, even though the Court of Appeals for the Ninth Circuit has called attention to "the DOE's minimal assessment of earthquake risks [in the 2002 EA for the LLNL BSL-3 facility] despite the presence of known, active faults that run directly under nearby Berkeley/Alameda County, California."[19] There is an earthquake fault zone less than 200 feet from the LLNL site boundary.

And with regard to the second situation, in which a public review and comment period is required where the nature of the proposed action is one without precedent, as specified above, the DOE does not currently operate any microbiological laboratories above Biosafety Level 2. Therefore, the construction and operation of BSL-3 facilities at both Lawrence Livermore National Laboratory and Los Alamos National Laboratory is clearly without precedent.

Finally, under the Department's Implementing Procedures, "DOE may issue a proposed FONSI for public review and comment in other situations as well."[20] In a similar situation, the U.S. Nuclear Regulatory Commission (NRC) recently published a supplemental EA and draft FONSI for a spent fuel storage facility under construction at the Diablo Canyon nuclear power plant in San Luis Obispo County, California, which included a 30-day comment period.[21] The NRC was forced to conduct the supplemental assessment after the Court of Appeals for the Ninth Circuit held that an EA that does not consider the environmental effects of a terrorist attack is inadequate.[22] Likewise, as discussed above, the Ninth Circuit held that the EA for the LLNL BSL-3 facility was inadequate because it contained no consideration of the effects of a terrorist attack.[23] Thus, even if the DOE determines that a public review and comment period is not required in this instance, the Department should do as the NRC has done and issue a proposed FONSI for public review and comment prior to making a final determination on the FONSI.

A Public Hearing on the Proposed BSL-3 Facility at LLNL Should Be Held

Since there have been no hearings on the proposed biowarfare agent research facility at LLNL, a public hearing should be held at which the public would have an opportunity to present comments and ask questions. Pursuant to the Council on Environmental Quality's NEPA regulations, "[a]gencies *shall* . . . [h]old or sponsor public hearings or public meetings whenever appropriate or in accordance with statutory requirements applicable to the agency. Criteria shall include whether there is . . . [s]ubstantial environmental controversy concerning the proposed action or substantial interest in holding the hearing."[24] There have been a number of incidents in the past several years that have raised grave concerns about the safety of such facilities. For instance:

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[19] *Id.*; *Tri-Valley CAREs*, No. 04-17232, slip op. at 3 n. 1.
[20] 10 C.F.R. § 1021.322(d) (1996).
[21] Nuclear Regulatory Commission, Supplement to the Environmental Assessment and Draft Finding of No Significant Impact Related to the Construction and Operation of the Diablo Canyon Independent Spent Fuel Storage Installation, 8 (May 2007).
[22] San Luis Obispo Mothers for Peace v. Nuclear Regulatory Commission, 449 F.3d 1016, 1035 (9th Cir. 2006), *cert. denied*, 127 S. Ct. 1124 (2007).
[23] *Tri-Valley CAREs*, No. 04-17232, slip op. at 4.
[24] 40 C.F.R. § 1506.6(c) (1978) (emphasis added).

- A report recently released by the CDC documented a number of serious problems with the biodefense research program at Texas A&M University, including unauthorized access to high-security laboratories, missing vials of infectious diseases, and failure to report the exposure of laboratory workers to dangerous biological agents.

- A graduate student working in a BSL-3 facility at the University of Mississippi Medical Center was treated for possible anthrax exposure following a laboratory accident on August 11, 2007.

- A faulty pipe connecting two world-class research facilities in the United Kingdom was determined to be the cause of an outbreak of foot and mouth disease on August 3, 2007.

- In 2004, while working on a vaccine to protect against bioterrorist attacks, three laboratory workers at Boston University were exposed to the bacteria that cause a rare disease called tularemia, or rabbit fever.

- In 2002, Army officials found evidence of multiple, accidental releases of anthrax spores in an Army biodefense research building at Fort Detrick, Maryland.

As a result of these unfortunate incidents, and others not mentioned, the U.S. House Committee on Energy and Commerce recently announced plans for a hearing in early October to examine the risks associated with the nation's growing number of BSL-3 and BSL-4 laboratories. This hearing and the publicity surrounding the releases and exposures from similar laboratories are likely to increase public awareness and anxiety about the safety of such facilities. In addition, the Department has received hundreds of requests for a hearing on the proposed LLNL Main Site BSL-3 facility from interested members of the public, as well as numerous community organizations. Accordingly, a hearing should be held to address the varied concerns about the adequacy of the safety regulations for the proposed BSL-3 facility.

Thank you for your time and consideration. If you have any questions or concerns about any of the matters contained in this letter or would like to further discuss these issues, please do not hesitate to contact me.

Sincerely,

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Thomas Paul D'Agostino, Administrator for the National Nuclear Security Administration
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Peace Justice Environment since 1983

October 29, 2007

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Re: Lawrence Livermore National Laboratory anthrax release and violations

Dear Mr. Brinker:

Tri-Valley CAREs is a non-profit organization founded in 1983 by Livermore area residents to research and conduct public education and advocacy regarding the potential environmental, health and proliferation impacts of the Department of Energy's (DOE) Lawrence Livermore National Laboratory (LLNL). On behalf of our 5,600 members, Tri-Valley CAREs urges DOE to further revise the Draft Revised Environmental Assessment (EA) for the proposed Biosafety Level 3 (BSL-3) facility at the Livermore Lab Main Site in a way that adequately analyzes the LLNL anthrax release and underlying security, safety and transportation violations. The Draft Revised EA should then be re-circulated for public comment. Finally, DOE should prepare an Environmental Impact Statement (EIS) for the proposed BSL-3 facility at LLNL.

I. The Livermore Lab anthrax release in September 2005

As you are no doubt aware, the University of California recently agreed to resolve its liability for an alleged violation of the Select Agent Program by Livermore Lab. In September 2005, LLNL transferred vials of anthrax to two laboratories located in Florida and Virginia. According to the Department of Health and Human Services (DHHS) Office of Inspector General (OIG), "[d]uring the transfers, anthrax was released from the shipped vials."[1] The OIG alleged that Livermore Lab violated the transfer requirements of the Select Agent Program by failing to comply with applicable shipping and packaging regulations. In addition, the OIG alleged that LLNL failed to comply with security and access requirements by allowing an unauthorized individual to have access to select agents in order to package the shipments of anthrax. Finally, the OIG alleged that Livermore Lab's Responsible Official failed to ensure

[1] Department of Health and Human Services Office of Inspector General, Fraud Prevention & Detection, Enforcement Actions, Administrative Actions, Civil Monetary Penalties, Select Agents and Toxins, http://www.oig.hhs.gov/fraud/enforcement/administrative/cmp/cmpitems.html#6 (last visited October 29, 2007).

compliance with the shipping and packaging requirements of the select agent regulations. LLNL agreed to pay the OIG $450,000 to resolve the above allegations.

II. The description of the anthrax release in the Draft Revised EA for the proposed BSL-3 facility is inadequate and incomplete

As a result of litigation initiated by Tri-Valley CAREs et al., the United States Court of Appeals for the Ninth Circuit ordered DOE to consider whether the threat of potential terrorist activity necessitates the preparation of an EIS for the proposed BSL-3 facility at LLNL.[2] In response to this ruling and guidance from DOE, the National Nuclear Security Administration (NNSA) revised the 2002 EA for the proposed BSL-3 facility to consider the potential impacts of terrorist activity. In addition, NNSA also made other updates to the 2002 EA, including the addition of a section describing a violation of Department of Transportation (DOT) shipping requirements by Livermore Lab in September 2005.

This additional section, which is in fact describing the LLNL anthrax release in September 2005, is wholly inadequate and any agency decision making based upon it will likely be deemed arbitrary and capricious by a reviewing court. First and foremost, this section severely downplays the significance of the anthrax release. For instance, there is no mention that anthrax was involved, that the anthrax was packaged by an unauthorized individual, or that LLNL's Responsible Official failed to ensure compliance with the shipping and packaging requirements of the Select Agent Program. Instead, NNSA claimed that, "[u]pon receipt, it was determined that the inner packaging of the[] shipments violated DOT packaging requirements and that the labels were missing important information."[3] Such a cursory and misleading analysis surely cannot form the basis for the conclusion that follows: "Accidents due to transportation of microorganisms are not expected to increase due to the Proposed Action."[4]

NNSA also argued that "[t]he addition of millimeter-quantity samples shipped to and from the BSL-3 facility . . . would not be expected to change the overall incidence of risk of transportation accidents."[5] With regard to the anthrax release in September 2005, the two shipments from Livermore Lab contained a total of approximately 4,025 vials of anthrax, hardly meager quantities.[6] The operation of a BSL-3 facility at LLNL would necessitate both increased and deadlier shipments of select agents to and from Livermore Lab. Accordingly, there is no support for the above assertion that the overall incidence of risk of transportation accidents would not be expected to change if the proposed BSL-3 facility becomes operational.

Moreover, NNSA claimed that "[t]he consequences of [any] such accidents would be anticipated to be minor, based on historical data."[7] While LLNL was fortunate that no known fatalities resulted from the anthrax release in September 2005, two workers were treated with the antibiotic Cipro after opening a shipment from Livermore Lab and discovering two uncapped

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[2] Tri-Valley CAREs v. Department of Energy, No. 04-17232, mem. op. at 4 (9th Cir. 2006).
[3] Department of Energy, Draft Revised Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California 57 (2007).
[4] *Id.*
[5] *Id.*
[6] Jaxon Van Derbeken, *Lab fined $450,000 for mishandling anthrax*, S.F. CHRONICLE, Oct. 7, 2007.
[7] Department of Energy, *supra* note 3, at 57.

vials of anthrax and one additional vial with a loose cap.[8] If the packaging deficiencies led to the release of anthrax while in transit, an untold number of individuals may have been exposed. This concern is amplified by the fact that biological materials or infectious agents could be shipped to and from the proposed BSL-3 facility by the U.S. Postal Service and commercial package delivery services.[9] These issues underscore the gravity of the anthrax release and its implications with regard to the consequences of such accidents.

As a related matter, recent reports have indicated that BSL-3 and BSL-4 laboratories in the United States "have experienced more than 100 accidents and missing shipments since 2003, and the number is increasing steadily as more labs across the country are approved to do the work."[10] A report by the Government Accountability Office documented "a major proliferation of high-containment BSL-3 and BSL-4 labs" in recent years, which calls into question the need for the proposed BSL-3 at LLNL.[11] Moreover, at a recent hearing by the House Energy and Commerce investigations subcommittee, federal officials "said that the expansion of the [biodefense] program over the last few years, coupled with a lack of training of lab workers and poor reporting of lab accidents, posed a potential threat to national security and public health."[12] These issues should also be analyzed in the Draft Revised EA.

Finally, and perhaps of greatest significance, the anthrax release highlights and validates the concerns expressed by Tri-Valley CAREs et al. and the Ninth Circuit with regard to the threat of terrorist attack on the proposed BSL-3 facility. As specified above, the OIG alleged that Livermore Lab failed to comply with security and access requirements by allowing an individual not authorized to have access to select agents to package the shipments of anthrax. This runs directly counter to the assertion by NNSA in the Draft Revised EA that "[o]nly personnel on LLNL's CDC registration are allowed to handle [select] agents."[13] After acknowledging that "the theft of pathogenic materials by an insider could have very serious consequences," NNSA concluded in the Draft Revised EA that "this scenario is not expected to occur at LLNL due to human reliability programs, security procedures, and management controls at the facility and the laboratory."[14] With regard to the anthrax release in September 2005, both the security procedures and management controls failed. As such, the Draft Revised EA should be further revised to adequately analyze the LLNL anthrax release and associated violations. For example, instead of ignoring known failures regarding personnel practices, the Draft Revised EA should acknowledge these failures and analyze in appropriate detail how they will be remedied.

III. Compliance with the National Environmental Policy Act

In order to comply with the National Environmental Policy Act (NEPA), DOE should further revise the Draft Revised EA in a way that adequately analyzes the Livermore Lab anthrax release and related violations. Subsequently, the Draft Revised EA should be re-circulated for

[8] Van Derbeken, *supra* note 6.
[9] Department of Energy, *supra* note 3, at 22.
[10] The Associated Press, *U.S. Labs Mishandling Deadly Germs*, N.Y. TIMES, October 2, 2007.
[11] Government Accountability Office, High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States, Highlights (2007).
[12] Jia-Rui Chong, *Experts detail risks of bioagent program*, L.A. TIMES, October 5, 2007.
[13] Department of Energy, *supra* note 3, at 65.
[14] *Id.* at 66.

public comment. DOE should then prepare an Environmental Impact Statement (EIS) for the proposed BSL-3 facility at the Livermore Lab Main Site because the proposed BSL-3 facility is a "major Federal action[] significantly affecting the quality of the human environment."[15]

Federal agencies have "a continuing duty to gather and evaluate new information relevant to the environmental impact of [their] actions."[16] Under the Council on Environmental Quality (CEQ) regulations for implementing NEPA, agencies shall prepare supplements to either draft or final EISs if "[t]here are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts."[17] The standard for supplementing an EA is the same as for an EIS.[18]

The LLNL anthrax release and associated violations provide significant information relevant to environmental concerns bearing on the proposed BSL-3 facility and its impacts. Specifically, this incident highlights the inherent security risks and dangers involved in the transportation of select agents to and from Livermore Lab; dangers that would only increase if the proposed BSL-3 facility becomes operational. As noted, the fact that an unauthorized individual was allowed access to select agent material is directly relevant to the analysis of potential terrorist attacks that was prompted by the Ninth Circuit's ruling.

Among the purposes of NEPA is to "[e]ncourage and facilitate public involvement in decisions which affect the quality of the human environment."[19] Because the Draft Revised EA for the proposed BSL-3 facility at the Livermore Lab Main Site contained a woefully inadequate and incomplete description and analysis of the anthrax release in September 2005, the involvement of the public was effectively circumvented. As such, DOE should further revise the Draft Revised EA so that the public is able to fully assess the magnitude of the anthrax release in a way that will lead to meaningful and substantive public comments. At a minimum, the public comment period should last at least thirty (30) days.

In order to comply with NEPA, the Draft Revised EA for the proposed BSL-3 facility at LLNL should be further revised and re-circulated for public comment. DOE should then acknowledge that the proposed facility will significantly affect the quality of the human environment, thereby necessitating the preparation of an EIS.

IV. Conclusion

In light of the above, it is clear that the Draft Revised EA for the proposed BSL-3 facility at LLNL is inadequate and should be further revised to analyze the Livermore Lab anthrax release

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[15] 42 U.S.C. § 4332(C) (1975).
[16] Warm Springs Dam Task Force v. Gribble, 621 F.2d 1017, 1024 (9th Cir. 1980) (citing 42 U.S.C. § 4332(2)(A-B); Essex County Preservation Ass'n v. Campbell, 536 F.2d 956, 960-61 (1st Cir. 1976); Society for Animal Rights, Inc. v. Schlesinger, 512 F.2d 915, 917-18 (D.C.Cir.1975)).
[17] 40 C.F.R. § 1509(c)(1)(ii) (1978).
[18] Idaho Sporting Congress, Inc. v. Alexander, 222 F.3d 562, 566 n.2 (9th Cir. 2000) (citations omitted); *see* Price Rd. Neighborhood Ass'n v. United States DOT, 113 F.3d 1505, 1509-10 (9th Cir. 1997); Friends of the Bow v. Thompson, 124 F.3d 1210, 1218 n.3 (10th Cir. 1997) (citations omitted); Clinch Coalition v. Damon, 316 F. Supp. 2d 364, 376 (D. Va. 2004) (citations omitted).
[19] *Id.* at § 1500.2(d).

and related violations in September 2005. The Draft Revised EA should then be re-circulated for public comment. Subsequently, an EIS should be prepared for the proposed BSL-3 facility.

Thank you for your time and consideration. If you have any questions or concerns about any of the matters contained in this letter or would like to further discuss these issues, please do not hesitate to contact me.

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Media Statement

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FOR I

LLNL Statement on DHHS Notice of Violation

Lawrence Livermore National Laboratory has reached a $450,000 settlement agreement with th Health and Human Services, Office of the Inspector General (OIG). The agreement concerns vi for Disease Control's (CDC) select agent regulations and involves errors in two shipments of *bac* back to September 2005.

In this particular situation, LLNL sent a shipment that had been inappropriately packaged and an incorrect paperwork. Upon discovery, we voluntarily suspended all select agent research for sev aggressive action to correct the issues. We conducted an extensive review to ensure that new p and training now preclude the acknowledged errors and that our practices effectively protect botl the general public.

Subsequently, the Centers for Disease Control (CDC) issued our laboratory a three-year renewa registration — without restriction. This renewal came in April 2006 following a CDC inspection of practices and procedures. The registration allows our laboratory to continue necessary research nation. We have conducted research and worked with biological level agents since the 1960's ar agents since 2000.

Best management practices involving the use of select agents and the safety, protection and cor employees and the general public is and will continue to be a top priority at our laboratory.

Founded in 1952, Lawrence Livermore National Laboratory has a mission to ensure national sec science and technology to the important issues of our time. Lawrence Livermore National Labor Lawrence Livermore National Security, LLC for the U.S. Department of Energy's National Nuclea Administration.

Exhibit 2

Attached to Notice of Lodging of Supp. to the Administrative Record
08-cv-1372-SBA

Revised Index of the Admin Record (AR) for the BSL-3 Facility

AR1 Final EA for the Proposed Construction and Operation of a BSL-3 Facility at LLNL, DOE/EA-1442, December 2002

AR2 Draft EA for the Proposed Construction and Operation of a BSL-3 Facility at LLNL, DOE/EA-1442, July 2002

AR3 ABSA 1998: American Biological Safety Association, "Risk Group Classification for Infectious Agents," Revision 1.0 from ABSA website http://www.absa.org/riskgroups/ (downloaded March 14, 2001).

AR4 ACGIH 2000: American Conference of Governmental Industrial Hygienists (ACGIH), "2000 TLV's and BEIs; Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices," Cincinnati, OH, pages 112-114 ACGIH (2000).

AR5 ANSI 1983: American National Standards Institute, "Specifications for Sound Level Meters," ANSI S1.4-1983 (1983).

AR6 ANSI 1998: American National Standards Institute, "Accessible and Usable Buildings and Facilities," ANSI A177.1-1998 (February 13, 1998).

AR7 Bascom 1996: Rebecca Bascom, MD, MPH, University of Maryland, "Occupational Health Programs," Proceedings of the 4th National Symposium on Biosafety, "Working Safety with Research Animals," Atlanta, GA (January 27-31, 1996)

AR8 Benenson 1959: Excerpt from Abram. S. Benenson, "Q fever vaccine: efficacy and present status; Medical Science Publication No. 6, Symposium on Q Fever," AGO 10047B, Superintendent of Documents, U.S. Government Printing Office, Washington, DC (1959).

AR9 Benenson 1995: Abram S. Benenson Editor, "Control of Communicable Diseases Manual," American Public Health Association, Sixteenth Edition (1995).

AR10 BLS 2001: U.S. Bureau of Labor Statistics, "Safety and Health Statistics," available on-line at http://stats.bls.gov/blshome.htm.

AR11 BMI 1993: Battelle Memorial Institute "Environmental Assessment for the BL-3 Laboratory at Battelle's Medical Research and Evaluation Facility," West Jefferson, OH (June 1993).

AR12 Burden and Sims 1999: David S. Burden and Judith L. Sims, "Fundamentals of Soils Science as Applicable to Management of Hazardous Wastes," U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response, EPA/540/S-98/500 (April 1999).

AR13 BWC 1972: U.S. Department of State, "Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin

Weapons and on Their Destruction,"
http://www.state.gov/www/global/arms/treaties/bwc1.html.

AR14 Cantor 1996: L. Cantor, "Environmental Impact Assessment," McGraw Hill, Inc., Second Edition (1996).

AR15 CDC 1974: Centers for Disease Control, "Classification of Etiologic Agents on the Basis of Hazard," U.S. Department of Health, Education, and Welfare, Public Health Service, CDC, Fourth Edition (1974).

AR16 CDC 1999: Centers for Disease Control and Prevention, "Biosafety in Microbiological and Biomedical Laboratories," U.S. Department of Health and Human Services, Public Health Service, CDC and National Institutes of Health (NIH), Fourth Edition, Washington, DC (April 1999).

AR17 CDC 2000a: Centers for Disease Control and Prevention, "Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response; Recommendations of the CDC Strategic Planning Workgroup," U.S. Department of Health and Human Services, CDC, Morbidity and Mortality Weekly Report (MMWR); Recommendations and Reports, Vol. 49, No. RR-4 (April 21, 2000).

AR18 CDC 2000b: Centers for Disease Control and Prevention, "Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets," U.S. Department of Health and Human Services, Public Health Service, CDC and NIH, Washington, DC (September 2000).

AR19 CDC 2000c: Centers for Disease Control and Prevention, "Laboratory-Acquired Human Glanders – Maryland, May 2000," U.S. Department of Health and Human Services, CDC, Morbidity and Mortality Weekly Report (MMWR), Vol. 49, No. 24 (June 23, 2000).

AR20 CDC 2001b: Centers for Disease Control and Prevention, "Q Fever," U.S. Department of Health and Human Services, Public Health Service, Viral and Rickettsial Zoonoses Branch, available on-line at: http://www.cdc.gov/ncidod/dvrd/qfever/index.htm (downloaded July 2, 2001).

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AR22 Cieslak and Eitzen 1999: Theodore J. Cieslak and Edward M. Eitzen Jr., "Clinical and Epidemiologic Principles of Anthrax," Centers for Disease Control and Prevention, Emerging Infectious Diseases, Vol. 5, No. 4, pages 552-555 (July-August 1999).

AR23 City of Livermore 2000: City of Livermore, CA, "Livermore Planning and Zoning Code," A Codification of the Planning and Zoning Ordinances of the City of Livermore, CA, Code Publishing Co., Seattle, WA (2000).

AR24 Coker et al. 1998: Excerpt from P.R. Coker, K. L. Smith, and M. E. Hugh-Jones, "The Status of Anthrax in the USA," and M. Hugh-Jones, "1996-97 Global Anthrax Report", Proceedings of the Third International Conference on Anthrax, Plymouth, England, Vol. 44 (September 7-11, 1998).

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AR26 Collins and Kennedy 1999: Excerpt from C. H. Collins and D. A. Kennedy, "Laboratory-Acquired Infections; History, Incidence, Causes and Prevention," Fourth Edition, Butterworth-Heinemann, Woburn, MA (1999).

AR27 DA 1989: Department of the Army, U. S. Army Medical Research and Development Command (USAMRDC), Final Programmatic Environmental Impact Statement; Biological Defense Research Program," Fort Detrick, Frederick, MD (April 1989).

AR28 DA 1992: Department of the Army, U.S. Army Dugway Proving Ground, "Final Environmental Impact Statement, Life Sciences Test Facility, Dugway Proving Ground, Utah," Dynamac Corporation, Rockville, MD (March 1992).

AR29 DA 1996: Department of the Army, Walter Reed Army Institute of Research, "Environmental Assessment, Biological Defense Research Program at the Armed Forces Institute of Pathology," United States Army Medical Research and Materiel Command, Fort Detrick, Fredrick, MD (April 1996).

AR30 DOE 1984: U.S. Department of Energy, "Environmental Protection, Safety, and Health Protection Standards," DOE Order 5480.4 (April 15, 1984 with change January 7, 1993).

AR31 DOE 1992: U.S. Department of Energy, "Final Environmental Impact Statement and Environmental Impact Report for the Continued Operation of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore, August 1992, DOE EIS-0157, U.S. Department of Energy (EIS), Washington, D.C., and University of California (EIR), SCH90030847 (1992).

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